Nevada State Immunization Program

Hospital Tdap and OB/GYN Cocooning Program

PROTOCOLS

July 1, 2015 – June 30, 2017

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Immunization Program

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This document has been created to help immunization providers follow all components of the Nevada Hospital Tdap & OB/GYN Cocooning Program. If you have any additional questions or need clarification, then please call (775) 684-5900 and/or e-mail nviz@health.nv.gov.

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PROGRAM ENROLLMENT

State supplied vaccines from the Nevada State Immunization Program (NSIP) are distributed, without charge, to hospital and obstetric provider sites that enroll in the NSIP's Cocooning Program. Each provider site must complete and return the completed/signed forms to the NSIP as requested. The provider must retain a copy of the completed enrollment form for three (3) years per federal reporting requirements as well as for future reference.

Re-Enrolling Providers:

- Complete the "Hospital Tdap and OB/GYN Cocooning Program Agreement to Participate;" and
- Complete and have on-site an "Office Vaccine Management Plan" (OVMP)
    - An OVMP Template may be accessed at: http://dpbh.nv.gov/Programs/VFC/dta/Forms/Vaccines_for_Children_(VFC)_Program_-_Forms/

New Providers:

- Complete the "Hospital Tdap and OB/GYN Cocooning Program Agreement to Participate;"
- Schedule an enrollment visit with NSIP staff; and
- Complete and have on-site an "Office Vaccine Management Plan" (OVMP)
    - An OVMP Template may be accessed at: http://dpbh.nv.gov/Programs/VFC/dta/Forms/Vaccines_for_Children_(VFC)_Program_-_Forms/

NOTE: PRACTICES WITH MULTIPLE CLINIC SITES MUST ENROLL EACH SITE AS A SEPARATE PROVIDER WITH A UNIQUE NSIP PIN.

REQUIREMENTS TO PARTICIPATE

By enrolling in the Cocooning Program, the provider site agrees to:

- Document vaccinations in records as required by the National Childhood Vaccine Injury Act (42 US Code 300aa-25). This law applies to all physicians that administer vaccines regardless of the age of the individual or the source of funding for the vaccine: https://www.law.cornell.edu/uscode/text/42/300aa-25
    - Date of vaccine administration;
    - Vaccine manufacturer and lot number;
    - Name and address, and if appropriate, the title of the health care provider administering the vaccine; and
    - Any other identifying information on the vaccine required pursuant to regulations promulgated by the Secretary of the Department of Health and Human Services.

- In addition, the following must be recorded:
    - Publication date of the appropriate Vaccine Information Statement (VIS); and
    - Date the VIS was given to the parent, legal guardian or individual of record.

- Adhere to the current Recommended Childhood and Adult Immunization Schedule as approved by the Centers for Disease Control and Prevention (CDC), Advisory Committee on Immunization Practices (ACIP); American Academy of Family Physicians (AAFP), the American College of Obstetricians and Gynecologists (ACOG), and the American College of Physicians (ACP);

- Comply with NSIP guidelines including, but not limited to notices regarding ACIP recommendations, vaccine shortages, restrictions on vaccine use, and use of new reporting forms;

- Maintain all records related to the Cocooning Program for a minimum of three (3) years, and make these records available to public health officials, upon request;
    - These records include, but are not limited to Special Projects Form 1: Vaccine Request and Accountability Report; Special Projects Form 2: Vaccine Lot Number Inventory Report; Special Projects Form 3: Nevada State Immunization Program Temperature Log; Vaccine Incident Report; VTrckS-UPS Pickup Request for Expired/Spoiled Vaccine; and the packing lists received with each vaccine shipment.

- Maintain clients' immunization records for a period required by NRS 629.051 and make such records available to the Nevada Department of Health and Human Services and/or the United States Department of Health and Human Services. Make such records available to the health authority and/or their designee, if requested (NAC 441A.750). This includes

collection of data for the "Quality Improvement Assessments." http://www.leg.state.nv.us/NRS/NRS-629.html#NRS629Sec051

- *#1…Each provider of health care shall retain the health care records of his or her patients as part of his or her regularly maintained records for 5 years after their receipt or production. Health care records may be retained in written form, or by microfilm or any other recognized form of size reduction, including, without limitation, microfiche, computer disc, magnetic tape, and optical disc… Health care records may be created, authenticated and stored in a computer system which limits access to those records.*
- *#7…A provider of health care shall not destroy the health care records of a person who is less than 23 years of age on the date of the proposed destruction of the records. The health care records of a person who has attained the age of 23 years may be destroyed in accordance with this section for those records which have been retained for at least 5 years or for any longer period provided by federal law.*

- Provide current Vaccine Information Statements (VIS) to the patient each time the patient receives an immunization, as required by federal law (42 US Code 300aa-25).
  - VIS's may be downloaded from: http://www.cdc.gov/vaccines/hcp/vis/ or http://www.immunize.org/vis/

- Not impose a charge for the cost of the vaccine;

- For adults 19 years and older, the administration fee should not exceed the regional Medicare vaccine administration fee of $21.34 per dose administered;

- Not refuse to administer a state supplied vaccine to any individual patient due to inability to pay the administration fee;

- Comply with the requirements for vaccine requests, vaccine accountability and vaccine storage and handling;

- Participate in Compliance Site Visits and immunization improvement activities in collaboration with NSIP staff as requested;

- Operate the Cocooning Program in a manner intended to avoid fraud and abuse; *(see Fraud & Abuse section for details)*

- Notify, in writing, the NSIP to terminate participation in the Cocooning Program;

- Utilize Nevada WebIZ, Nevada's immunization information system, to record all administered vaccinations for children and adults (per NRS 439.265 and corresponding NAC);
  - NRS: http://www.leg.state.nv.us/NRS/NRS-439.html#NRS439Sec265

  - NAC: http://www.leg.state.nv.us/Register/2009Register/R094-09A.pdf
  - NV WebIZ: http://dpbh.nv.gov/Programs/WebIZ/dta/Policies/WebIZ_-_Policies/

- Maintain proper storage and handling standards for vaccines as outlined in CDC's Vaccine Storage and Handling Toolkit, which covers the following: http://www.cdc.gov/vaccines/recs/storage/toolkit/default.htm
  - Use of a digital, unexpired calibrated thermometer OR digital data logger certified by an ILAC MRA signatory body or which meets ISO/IEC 17025 international standards;
  - Document twice daily the vaccine storage unit temperature and include actions taken for temperatures outside the recommended range;
  - Receive approval from the NSIP before transporting state supplied vaccines; and
  - Receive approval from the NSIP before moving state supplied vaccines into a new refrigerator.

- Notify the NSIP of all changes immediately as they occur including, but not limited to:
  - Change of address;
  - Change in shipping hours;
  - Change in the Primary or Backup Vaccine Coordinator position;
  - Change of telephone number;
  - Change of fax number;
  - Change in any contact e-mail addresses; and
  - Additions/deletions of physicians, PA's and nurse practitioners.

VACCINE REQUESTS & ACCOUNTABILITY

The NSIP processes enrolled provider's vaccine requests monthly per notification in each "NSIP Monthly Memo." The amount of vaccine approved is calculated by the provider's reported average monthly usage and most often a 60-day vaccine supply is allowed. Enrolled provider sites are required to submit vaccine inventory and accountability reports on a monthly basis indicating vaccine doses used and vaccine doses remaining in inventory. Enrolled provider sites must use and submit the most current reporting forms each month.

Completed Forms to be Submitted each Month by Enrolled Provider:

Special Projects Form 1: Vaccine Request and Accountability Report

- Complete all the heading information:
  - Facility Name: official name of the facility (do not abbreviate nor use physician name unless that is the legal name of the practice)
  - Primary Vaccine Coordinator (PVC) name
  - Direct phone line for PVC
  - NSIP PIN
- Reporting Period (always begins the first day of the month and ends the last day of the month);
- Denote "Beginning Inventory" (as of the 1st day of the reporting month and will be the same as the "End of Month Refrigerator Count" for the previous month). Please do not include privately purchased vaccines on NSIP reporting forms;
- Denote "Doses Received" (the state supplied vaccines received from McKesson during the reporting month);
- Denote "Doses Transferred In" (these are state supplied vaccines received from another NSIP-enrolled provider);
- Denote "Doses Administered" (how many doses of state supplied Tdap the facility administered during the reporting month);
- Denote "Doses Transferred Out" (these are state supplied vaccines the facility transferred to another NSIP-enrolled provider);
- Denote "Doses Expired or Wasted" (these are state supplied vaccines that expired or were spoiled/wasted during the reporting month and must be returned to McKesson using the proper paperwork);
- Denote "Ending Inventory" (this is the calculation of Column 1+Column 2+Column 3-Column 4-Column 5-Column 6 = Ending Inventory);
- Denote "End of Month Refrigerator Count" (this is the actual, physical count of vaccine doses remaining in the storage unit at the end of the reporting month); if the physical count does not match the "Ending Inventory," then the accountability paperwork must be reviewed and corrected;
- Denote the number of vaccine doses needed (NOT the number of vials or boxes);
- **If a discrepancy persists, then a memorandum must be sent to the NSIP with an explanation.**

Special Projects Form 2: Vaccine Lot Number Inventory Report

- Complete all the heading information:
  - Facility Name: official name of the facility (do not abbreviate nor use physician name unless that is the legal name of the practice)
  - Primary Vaccine Coordinator (PVC) name
  - Direct phone line for PVC
  - NSIP PIN
- Reporting Period (always begins the first day of the month and ends the last day of the month);
- You must report completely and accurately each lot number of state supplied vaccine that you have on hand on the last day of the reporting month;
- There is room to list up to three (3) lot numbers of any given vaccine on this form; if you have more than three (3) lots of any given vaccine, the you must use a second Form 2 page;
- The amounts listed in the "Total Inventory" column of Form 2 must match the "End of Month Refrigerator Count" on Form 1: Vaccine Request and Accountability Report.

Special Projects Form 3: Nevada State Immunization Program Temperature Log

- Complete all the heading information:
  - NSIP PIN
  - Facility Name: official name of the facility (do not abbreviate nor use physician name unless that is the legal name of the practice)
  - Reporting Month and Year
- Use a separate state supplied Temperature Log for each vaccine storage unit that holds state supplied vaccines;
- Write in the time that you are checking the temperature;
- Place an "X" in the box that corresponds with the current temperature and time of day (i.e., AM/PM) and initials of the staff person recording the temperature;
- FOR PRACTICES WITH MIN/MAX THERMOMETERS: During each morning reading, you must place an "O" in the box that corresponds with the maximum and minimum temperature reached since the last reset, and then reset the min/max function for the next morning;
- Write on the bottom right side of the form the expiration or recalibration date for each thermometer used to monitor a vaccine storage unit that contains state supplied vaccine; and
- **Take immediate action if the temperature you record is in the shaded zone as this represents an unacceptable temperature range and will damage the vaccines:**
  - Move the vaccine to proper storage conditions as quickly as possible;
  - Begin completing the Vaccine Incident Report (VIR);
  - Call the vaccine manufacturer(s) to determine vaccine viability;
  - Call the NSIP at (775) 684-5900 to report your progress;
  - Document the vaccine disposition per the manufacturer on the VIR; and
  - Fax the completed report and any back-up to the NSIP at (775) 684-8338.

Submitting Vaccine Requests

- Each month fax to the NSIP at (775) 684-8338:
  - Form 1: Vaccine Request and Accountability Report
  - Form 2: Vaccine Lot Number Inventory Report
  - Form 3: NSIP Temperature Log
- Incomplete reports will be returned for correction and may result in the vaccine request being placed on hold.
- Emergency requests are only allowed during disease outbreaks.
- Vaccines should arrive within ten (10) days of the Vaccine Request Confirmation.
- Providers are encouraged to maintain a 60-day vaccine inventory for both their public and private stock.
- If it is necessary for the office to submit a second vaccine request (e.g., you forgot to ask for something, etc.), then you must write "SUPPLEMENTAL" on the margins of Form 1 when you send in the second request. **If you fail to notify us that a request is supplemental to paperwork already submitted, then the supplemental request will be considered a duplicate and will be discarded.**

PROPER VACCINE STORAGE & HANDLING

Vaccine Storage and Handling Guidelines

Vaccine storage units must be selected carefully and used properly. Stand-alone refrigerators and freezers are the only units proven to consistently maintain required temperatures for safe vaccine storage. However, a combination refrigerator/freezer unit with two doors and two thermostat controls is acceptable for vaccine storage if only the refrigerator compartment is being used to store vaccine. Combination units do not maintain consistent in-range temperatures for the freezer compartment. The Centers for Disease Control and Prevention (CDC) recommends that any refrigerator or freezer being used for vaccine storage must:

1. **Be able to maintain required vaccine storage temperatures year-round;**
2. **Be large enough to hold the year's largest inventory (think about Back to School and Influenza Season);**
3. **Be monitored using the unexpired, calibrated digital data logger (LogTag TRED 30-7R) provided by the Nevada State Immunization Program; and**
4. **Be dedicated to the storage of vaccines or other biologics. Absolutely NO food or beverages should be stored in a vaccine storage unit at any time.**

IMPORTANT NOTE: If the NSIP Program Manager, Vaccine Manager, Provider Quality Assurance Manager, and/or the Vaccine Storage & Handling Coordinator has recommended (either verbally or in writing) to a Primary Vaccine Coordinator and/or Medical Director that the practice should purchase stand-alone vaccine storage units as a result of reviewing long-term temperature monitoring information, and the office does not purchase the recommended storage unit type, then the signing Medical Director WILL BE HELD ACCOUNTABLE for replacing all VFC vaccine doses (at private cost) that are spoiled or wasted as a result of temperature excursions in the non-recommended unit. Those replaced doses can then ONLY be administered to VFC-eligible patients (see the *Fraud & Abuse Policy*).

General Requirements

Vaccines that require temperatures between **35° and 46° F (2° and 8° C)** must be stored in the refrigerator compartment of a household or commercial-style refrigeration unit. Vaccines that require temperatures of **5° F (-15° C) or colder** must be stored in a stand-alone freezer. It is recommended that provider offices use separate units for vaccine storage, because stand-alone refrigerators and freezers maintain the required temperatures better than combination units intended for home use. Whatever type of unit is used, the refrigerator and freezer compartments must have separate external doors and separate thermostat controls. The storage unit must have enough room to store the year's largest vaccine order without the vaccines touching the back or sides of the unit's interior. It is recommended to store full water bottles in the refrigerator and frozen ice packs in the freezer to help stabilize the temperatures in the unit.

Vaccines are NOT to be stored in the door or crisper drawers of a storage unit.

For more information on vaccine storage: http://www.cdc.gov/vaccines/recs/storage/default.htm

UNACCEPTABLE VACCINE STORAGE UNITS

The following units are unacceptable for vaccine storage, even temporarily, no exceptions:

- "Dorm-style" units provide poor temperature control and often freezes vaccines that require refrigeration, resulting in immediate and irreversible damage. "Dorm-style" units are defined as small refrigerator/freezer combination units with a single external door and an evaporator plate or cooling coil that forms a small freezer compartment within the unit or is pulled across the internal back wall of the unit.

- Manual defrost (or cyclic defrost) refrigerators have significant temperature variations, often freezing and damaging vaccines. These units often have exposed cooling plates, coils or vertical plates on the interior back wall of the refrigerator. These may be covered with visible frost or ice.
- Convertible refrigerator-only units that have an internal switch to convert the "refrigerator-only" unit to a "freezer-only" unit.
- Any refrigeration or freezer unit that is over 10 years old.
- Small apartment size (4ft or below) units.

Dorm-Style Units: Small, single-door combined refrigerator/freezer units **should not be used** for any vaccine storage, even temporary. The freezer compartment in this type of unit is incapable of maintaining temperatures cold enough to store frozen vaccines. If attempts are made to cool the freezer to the appropriate temperature, then the temperature in the refrigerator will fall below the recommended range, potentially freezing the refrigerated vaccines.

ACCEPTABLE VACCINE STORAGE UNITS

The following types of vaccine storage units are accepted by the NSIP:

- **Stand-alone refrigerator unit(s) – recommended type**
- **Stand-alone freezer unit(s) – recommended type**
- Combination refrigerator/freezer unit with two (2) doors and two (2) thermostat controls;
- Combination refrigerator/freezer unit with two (2) doors and one (1) thermostat control, where only the refrigerator compartment is being used for vaccine storage; or
- Commercial combination self-defrosting unit with two (2) separate compressors, a thermostat control for each compartment and no circulating air between the freezer and refrigerator compartments.

Option 1: Stand-Alone, Under-the-Counter Refrigerator and Freezer Units

Stand-alone, under-the counter refrigerators and freezers are excellent choices for vaccine storage. Under-the-counter refrigerators and freezers are stand-alone units that allow for the separate storage of frozen and refrigerated vaccines. Stand-alone refrigeration units must also be self-defrosting and it is recommended that stand-alone freezer units be self-defrosting.

The benefits of using stand-alone units for vaccine storage include:

- **Lower risk of catastrophic inventory loss.** Separate compressors and condensers decrease the risk of total vaccine loss that might occur in a combination style unit.
- **Temperature stability.** Because these units are only required to hold a single set temperature, they are not constantly re-adjusting and circulating cold air between the refrigerator and freezer compartments.
- **No risk of accidentally freezing refrigerated vaccine.** Combined units often use a cold air vent from the freezer to regulate temperatures in the refrigerator compartment. This freezing air blows down on the top shelf of the refrigerator and can quickly freeze any vaccines stored underneath.

Providers have many options for finding affordable, office-appropriate stand-alone units. **Stand-alone units can be under-the-counter size as discussed here or full-size.** Office Managers can shop local home improvement stores (Home Depot, Lowes) or go for lab/pharmaceutical grade units (Panasonic, American Biotech Supply, Migali, etc.):

- www.homedepot.com – **search within appliances**
- www.lowes.com – **search within appliances**
- http://us.panasonic-healthcare.com/preservation/
- http://www.americanbiotechsupply.com/
- http://www.migaliscientific.com/products/vaccine-storage/

Option 2: Home-Style, Combination Refrigerator/Freezer Units

These types of units are most often found in home and appliance stores. Higher-end models are sometimes referred to as "commercial-grade" and are most often used in the food service industry. While not ideal for vaccine storage, many immunization clinics use this type of unit due to its affordability. **In 2015, providers that will be replacing a vaccine storage unit must purchase a stand-alone unit to remain compliant with NSIP vaccine storage and handling standards.** It is important for providers to choose an appropriate household model for storage of refrigerated vaccines. The unit must incorporate the characteristics detailed in the next paragraph.

Essential **features for a combination unit:**

- Refrigerator and freezer compartments must have separate external doors;
- Refrigerator and freezer compartments must each have a dedicated thermostat control;
- The shelves should be adjustable; and
- There should be enough room to store vaccines on the middle shelves (away from cool air vents).

Recommended **features for a combination unit:**

- Outside door locks (manufacturer installed only);
- Separate compressor units for each compartment;
- Automatic condensate removal, no drain lines;
- Forced air circulation;
- Door alarm if left open or ajar; and
- Battery back-up (in cases of power failure and no generator).

Risk of freezing vaccine – Never store freeze-sensitive vaccines near the cold air vent in the refrigerator compartment; cold air from the freezer will often blow down on the vaccine and freeze it, resulting in irreparable damage and wasted vaccine.

Single thermostat units – Home-style, combination refrigerators with a single thermostat are strongly discouraged. This type of unit is only acceptable if storing vaccine in the refrigerator compartment only. A single thermostat makes it difficult to maintain recommended temperatures in both compartments. **If you are thinking of purchasing a new unit – DO NOT purchase a single thermostat unit!!**

Option 3: Stand-Alone, Laboratory Grade Refrigerator and Freezer Units

Stand-alone, laboratory grade refrigerators and freezers are considered the gold standard for dedicated vaccine storage; they are considered the most secure. As with most "gold-standard" products, they carry a hefty price tag and are usually reserved for health departments, pharmacies, health laboratories and hospitals. However, many manufacturers also produce an array of refrigerators and freezers that may meet your clinic's vaccine storage needs at a lower cost. **Be aware that units with glass-front doors do not maintain cold temperatures during power outages as well as units with solid doors.**

TEMPERATURE MONITORING REQUIREMENTS IN NEVADA

Beginning January 1st, 2015, VFC Providers are required to purchase and maintain at least one (1) back-up thermometer with a current certificate of calibration and have it readily available. This back-up thermometer is to be used if the current temperature monitoring system fails or needs to be sent for recalibration.

If your office has not yet been provided a LogTag TRED 30-7R, then the thermometer that is used to monitor VFC vaccine storage units must:

- Have a digital display that can be read without opening the unit doors;
- Have a biosafe glycol-encased probe;
- Have current temperature and minimum/maximum temperature review functionality;
- Have an alarm (audible or visual) for out-of-range temperatures;
- Have an accuracy of +/- 1° F (0.5° C); and
- Have a low battery indicator.
- It is strongly recommended that clinics that are routinely closed for more than 2 consecutive days, and do not have office staff that assess and record temperatures twice a day when the office is closed, use digital data loggers with continuous monitoring and recording capabilities.

Biosafe Glycol-Encased Probes

The Centers for Disease Control and Prevention (CDC) **recommend use of a digital thermometer with a biosafe glycol-encased probe that will more closely approximate the measure of liquid temperature.** A temperature buffer enables a thermometer probe to more closely match the temperature changes experienced by liquid vaccine.

Examples of temperature buffers are a probe inserted into a glycol-filled vial or one inserted into glass beads (**glycol-filled vials are more strongly recommended)**. The NSIP requires this type of probe because studies by the National Institute of Standards and Technology (NIST) conducted in 2009 showed that compared to probes that measure ambient air temperature, the digital thermometer with glycol-encased probe more accurately reflects the temperature of the vaccine vial and does not register normal air temperature fluctuations which do not significantly impact vaccine temperature.

Because the main factor affecting potency of refrigerated vaccines is exposure to freezing temperatures, it is important that glycol-encased probes be placed among the vaccines in a central part of the vaccine storage unit instead of on a unit's interior wall; and at least for refrigerated vaccines, in the part of the refrigerator where manufacturer recommended vaccine storage temperatures can best be maintained.

In addition to the use of a digital thermometer in a glycol-filled vial, the recommended temperature monitor should also provide continuous data monitoring information in an active display and be placed on the outside of the unit to allow for reading temperatures without opening the unit door.

Thermometer Calibration Requirements

To ensure validity of temperature measurements, only calibrated thermometers with a certificate of Traceability and Calibration performed by a laboratory accredited by an ILAC-MRA signatory body or an entity that provides documentation showing calibration testing that meets ISO/IEC 17025 international standards should be used. **Using currently calibrated thermometers continues to be a requirement for VFC Providers.**

Digital Data Loggers for Temperature Monitoring

The Nevada State Immunization Program is providing all enrolled VFC providers with at least two (2) LogTag TRED 30-7R data logger units by the end of 2015.

In addition to the use of a digital thermometer with a biosafe glycol-encased probe, the thermometer should also be able to provide and store data monitoring information set at programmable intervals in an active display that allows for reading temperatures without opening the unit door. This means that the digital data logging thermometer probe should be able to remain in place and not be disturbed during data reading and recording. A detachable probe facilitates downloading temperature data without removing the probe from the storage unit, and should simplify daily use and minimize operator cause of temperature variability. The digital data logger should also include the following:

- Hi/low alarm for out of range temperatures
- Current temperatures as well as min/max temperatures
- Low battery indicator
- Accuracy of +/- 1˚F (5˚C)
- Memory storage of at 4000 readings, the device cannot rewrite over old data, and stops recording when the memory is full, and;
- Has a user programmable logging interval, (or reading rate).

Refrigerated Vaccines

The temperature of all refrigerated vaccine must remain steady between 35°F and 46°F (2°C and 8°C). **The recommended temperature for refrigerated vaccines is 40°F.** The vaccines are shipped with ice packs and bubble wrap to protect the vaccines from contact with the frozen ice packs.

Temperature Checks

This details the policy for those offices not using the LogTags. Refrigerator and freezer temperatures must be checked a minimum of twice daily on business days and documented on the graph-style Form 4: "Nevada State Immunization Program Temperature Log." It is strongly recommended that providers be using a thermometer that includes a minimum/maximum function. If the provider is using a min/max thermometer, then the minimum and maximum temperatures must be recorded on the Temperature Log each morning and reset to be checked the next morning of business. Providers are required to maintain temperature logs on file for at least three (3) years.

Vaccine Restitution Policy

The Nevada State Immunization Program is authorized to request dose-for-dose reimbursement from an enrolled provider for the value of publicly-supplied vaccines wasted through negligent storage or otherwise non-compliant practices that do not meet federal/state VFC Program requirements. Dose-for-dose reimbursement means the provider must purchase replacement vaccine using their own private funds at private vaccine cost; additionally, replaced vaccine must be used to vaccinate VFC eligible children only. The NSIP is NOT authorized to accept financial reimbursement as restitution for wasted/spoiled vaccine.

ADDITIONAL REQUIREMENTS FOR VACCINE STORAGE & HANDLING

- The provider must have a current "Office Vaccine Management Plan." A template can be located on our website: http://dpbh.nv.gov/Programs/VFC/dta/Forms/Vaccines_for_Children_(VFC)_Program_-_Forms/
- Food must not be stored in any units being used for vaccine storage;
- Vaccines must not be stored in the drawers, doors or on the floor of a unit;
- Vaccines must be stored in the refrigerator away from any cool air vents that may be connected to the freezer compartment (combination units only);
- Vaccines must be stacked with at least 2in of air space between the boxes and the side/back walls of the unit to allow air circulation;
- Vaccine must be stored in its original box unit use;
- Bottles of water should be stored in the lowest compartment of the refrigerator and extra ice packs stored in the freezer to help maintain temperatures in cases of power outage. No ice packs in the doors of the freezer.
- State-supplied vaccine may be stored in the same unit as privately purchased vaccine, but both stocks must be clearly labeled for easy identification by staff;
- Inventory must be rotated to ensure that the shortest dated vaccine is used first;
- State-supplied vaccine with short expiration dates (expiring within 3 months) should be reported to the NSIP if the provider does not anticipate using these vaccines before expiration. When notified that short-dated vaccines will not be used, the NSIP will make every effort to have the vaccines transferred to another enrolled provider for immediate use;
- Post "DO NOT DISCONNECT" signs on the front of each vaccine storage unit, next to the storage units' electrical outlet (if exposed) and on the breaker switch that supplies power to the vaccine storage unit(s);
- The vaccine storage unit(s) must be plugged directly into an electrical outlet (surge protectors are NOT to be used); and
- Providers are strongly encouraged to have all staff responsible for vaccine storage and handling review and apply the practices for proper vaccine storage and handling found on the CDC's website: http://www.cdc.gov/vaccines/recs/storage/default.htm.

Receiving Vaccine Shipments

All staff in the facility must be trained in vaccine receipt and management (including, but not limited to):

- Front desk staff
- Medical staff
- Purchasing staff
- Security staff, etc.

All staff who may accept packages for the clinic must be aware that vaccine shipments require immediate attention

Receiving Refrigerated Vaccines

- The staff person accepting the shipment must immediately notify the office's primary vaccine coordinator or designated backup;
- The box containing the vaccines must be physically handed to the office's primary vaccine coordinator or designated backup;
- Immediately upon shipment receipt, remove both temperature monitors included in the shipment:
    - 3M MonitorMark to determine if the shipment may have been subjected to warmer temperatures; and
    - TransTracker C FREEZEmarker Indicator to determine if the shipment may have been subjected to colder temperatures.
- Follow the monitor instructions on each card regarding activation and reading;
- If you have any questions or concerns when reading the monitor, if the monitor is not activated, or if you see damage to the package, then contact McKesson at 877-836-7123 **within 2 hours** and notify the NSIP;
- Check the condition of the vaccines;
- Compare the "packing list" to the actual contents of the shipment. Any discrepancies and/or damage must be reported immediately to the NSIP at (775) 684-5939.
    - If there are any discrepancies with the packing slip or concerns about the shipment, then immediately mark the vaccine and diluents as "DO NOT USE" and store them in proper conditions until manufacturer disposition is acquired.
- Refrigerate the vaccines immediately and place those with the shortest expiration date in front to be administered first.

VACCINE EXPOSURE TO IMPROPER TEMPERATURES AT PROVIDER OFFICE

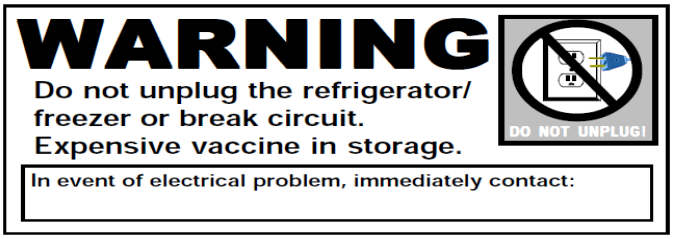
- Immediately place the vaccine into proper storage conditions and label "Do Not Use;"
- Do not presume that the vaccine has been compromised;
- Begin completing the "Vaccine Incident Report";
- Call the manufacturers to assess whether vaccine potency could have been affected;
    - Also contact the NSIP at (775) 684-5939;
- Document viability and disposition per the manufacturer on the "Vaccine Incident Report;"

- Document corrective action steps taken on the "Vaccine Incident Report;" and
- Fax the completed "Vaccine Incident Report" to the NSIP at (775) 684-8338.
- If the vaccines are determined to be non-viable by the manufacturer, then follow the instructions below: "Steps for Returning Expired/Spoiled Vaccine to McKesson."
- **If the NSIP determines the vaccines were administered after exposure to damaging storage conditions, then the NSIP strongly recommends that patients/parents/guardians of the vaccine recipients be notified by the provider and offered re-vaccination to ensure they are fully immunized.**

SETTING UP A NEW VACCINE STORAGE UNIT

Before placing vaccines in a new unit, follow these steps to ensure success:

- Make arrangements in advance to temporarily store your vaccines in an appropriate, alternate storage unit with unexpired, calibrated thermometers. Monitor the temperature of this temporary unit a minimum of twice daily and maintain stable temperature readings within the target ranges (refrigerator: 40°F and freezer: 5°F or <5°F) until the new unit is approved;
- Monitor the temperature of the new unit twice daily for five (5) business days before placing vaccines within. Obtain approval from the NSIP prior to transferring vaccines into the new unit;
- Your new unit may have colder and warmer areas especially in the refrigerator compartment. A best practice is to check the temperatures in different areas of the compartment prior to vaccine storage in order to determine the most stable area for vaccine storage;
- Plug the new vaccine storage unit directly into a wall or floor outlet. **Never use extension cords or power strips;**
- If your new unit comes with vegetable bins, then fill them with full bottles of water. Do not store vaccines in the refrigerator doors, the vegetable bins, or on the floor of the unit;
- Add additional full bottles of water to the shelves inside the refrigerator door and store ice packs in the freezer. These measures will help maintain a stable, cold temperature if the refrigerator or freezer doors are opened frequently or in cases of power failure;
- Place digital unexpired, calibrated thermometers (with glycol-enclosed probes) in the center of each unit close to where the vaccine will be stored. Any thermometer being used, including built-in thermometers in pharmacy and lab-grade units, must have a certificate of calibration proving it has been calibrated to ISO/IEC 17025 standards;
- Set the refrigerator temperature to stabilize around 40°F and set the freezer temperature to stabilize around 3°F or lower. Adjust the temperature in small increments and continue to monitor the units until the target temperatures are reached;
- Carefully label the areas where vaccine will be stored. Identify where state supplied vaccine will be versus where privately purchased vaccine will be stored within the unit;
- Be sure a DO NOT UNPLUG sticker is posted on the front of the unit(s), near the electrical outlet(s), and label the appropriate circuit breaker(s): "Expensive Vaccines, Do Not Disconnect."



RETURNING EXPIRED/WASTED VACCINES

The Following Items Should NEVER Be Returned to McKesson

- Syringes that you filled but did not use;
- Any used syringes with or without needles attached;
- Broken vials; or
- Any multi-dose vial from which some doses have been withdrawn.

The items listed above should be disposed of according to usual medical biosafety procedures.

Do not return empty shipping boxes to McKesson Specialty Distribution. Providers are encouraged to recycle the boxes through their local recycling programs. McKesson Specialty Distribution recommends that providers keep one or two boxes on hand for use in returning non- viable (expired, wasted, spoiled) vaccine.

What Should Be Returned to McKesson?

- Spoiled or expired product in its original vial;
- Unused pre-filled syringes from manufacturers with NDC printed on them; and
- Expired or compromised VFC/CHIP/317/STATE vaccine must be reported to the NSIP using the appropriate forms (Vaccine Request and Accountability Report).

Receiving Return Labels via E-Mail

- Complete the "VTrckS-UPS Pickup Request for Expired/Spoiled Vaccine" (for the products eligible for return) and fax the completed form to (775) 684-8338;
- Pack the non-viable VFC vaccines in any box for return to McKesson (do not add any private stock vaccines);
- Once the NSIP receives the pickup request, we will contact McKesson to send you mailing label(s) via e-mail. The e-mail will go to the person NSIP has on file as the Primary Vaccine Coordinator for your clinic. There are specific guidelines you must follow when receiving the label(s):
    - The e-mail address from which the label arrives is uoltsupport@usp.com and in the subject line it will say "UPS Shipping API";
    - Once NSIP inputs the label request into VTrckS, Tammy Brown will fax your request back with verification that the label was ordered. Once you receive the fax, the label should arrive in your inbox approximately 30 – 60 minutes later. Check your spam/junk folder if you don't see the label in your inbox within that time.
    - **One label will arrive per e-mail.** If you have two boxes of vaccine to return, then you will receive two separate e-mails with one label per e-mail;
    - If you ordered two labels but only use one, then you must put the unused shipping label in the box that is being shipped to McKesson;
    - You cannot photocopy or reprint the label to use at a later time on another shipment.

Steps for Returning Expired/Spoiled Vaccines via USPS Mail

- Complete the "VTrckS-UPS Pickup Request for Expired/Spoiled Vaccine" (for the products eligible for return) and fax the completed form to (775) 684-8338;
- Pack the non-viable VFC vaccines in any box for return to McKesson (do not add any private stock vaccines);
- Once the NSIP receives the pickup request, we will contact McKesson to send you mailing label(s) via normal mail (below is an example of the envelope for mailing labels that you will receive at your office);
- After your office receives the mailing labels, contact a UPS driver for pickup; and
- Keep a copy of all vaccine return paperwork for up to three (3) years.

EMERGENCY EVENT STORAGE & HANDLING

The following procedures should be performed in the event of a power outage:

Short-Term Power Outage

- Record the time and temperature of the room, refrigerator and freezer using an unexpired, calibrated thermometer;
- If it is determined the power will only be out for a few hours, then tape the unit doors so no one can inadvertently open them and allow cold air to escape;
- When the power resumes, record the time and the temperatures in the refrigerator and freezer. If the temperatures are out of range, then do not use the vaccine; and
- Contact the NSIP Vaccine Manager and the vaccine manufacturers for instructions if VFC/state supplied vaccines are involved.

Long-Term Power Outages

Facilities WITH a backup generator:

- Record the time and temperature of the room, refrigerator and freezer using an unexpired, calibrated thermometer;
- Ensure the vaccine storage unit is plugged in an outlet that is supplied by the generator;
- Once the generator is supplying power to the storage unit, record the temperatures in the room, refrigerator and freezer again; and
- If the generator is not functioning, then prepare to transfer the vaccine to a functioning unit.

Facilities WITHOUT a backup generator:

- Record the time and temperature of the room, refrigerator and freezer using an unexpired, calibrated thermometer;
- Gather cooler boxes, ice packs, bubble wrap and cardboard to pack the vaccines:
- Place frozen ice packs in the bottom of the cooler boxes;
- Place cardboard and then bubble wrap on top of the frozen ice packs;
- Place the refrigerated vaccines on top of the bubble wrap;
- Place an unexpired, calibrated thermometer in the middle with the vaccines;
- Put another layer of bubble wrap and then cardboard on top of the vaccines;
- Place another layer of frozen ice packs on top of the cardboard; and
- Place the lid of the cooler box on the cooler and secure it with tape.
- **Frozen vaccines must be placed in a separate cooler box directly on frozen ice packs and surrounded by additional ice packs.**
- **Transport the vaccines to another location that has been coordinated with and not affected by the disaster in the CAB of a vehicle. NEVER transport vaccine in the trunk of a vehicle.**

Complete a Vaccine Incident Report and fax it to the NSIP as soon as possible at (775) 684-8338.

In the event of a mechanical failure

- Record the time and temperature of the room and the affected storage unit using an unexpired, calibrated thermometer; then
    - Pack the vaccine in a bag and mark it "DO NOT USE";
    - Place the vaccine in another freezer or refrigerator if the provider has more than one storage unit;
- Call each vaccine manufacturer and follow their directions to determine vaccine viability;
- Complete a Vaccine Incident Report immediately and fax it to the Nevada State Immunization Program. Ensure the report details if your vaccine is viable or spoiled; then
- Complete the "VTrckS-UPS Pickup Request for Expired/Spoiled Vaccine" and fax to the NSIP at (775) 684-8338 to obtain a mailing label for return;
- Have the affected storage unit repaired or replaced;
    - Complete 5 business days of temperature monitoring on the affected or new unit; then
    - Fax the Temperature Log or Log Tag information to the Nevada State Immunization Program to obtain permission to return the vaccine to the affected unit; and
- Continue to monitor temperatures twice daily to ensure the repaired or new unit stays within the proper temperature ranges for continuous vaccine storage.

REQUEST FOR TERMINATION

An enrolled provider may request to terminate their Agreement to Participate at any time and must provide:

- Written notification on office letterhead including:
  - Date participation in the NSIP will cease;
  - Reason for termination;
  - Ending inventory of the state supplied vaccines on hand including:
    - Lot Numbers,
    - Expiration Dates,
    - Number of doses; and
    - Current "Temperature Log"

Upon receipt of this notification, the NSIP will inactivate the provider as requested and the local health department will transfer any viable vaccines to another enrolled provider.

An inactive provider may request to be re-activated at any time; however, state-supplied vaccines may not be requested by the re-activated provider until re-enrollment paperwork has been completed, a re-enrollment visit has been conducted, and the site is approved as being in compliance with current NSIP Protocols.

VACCINE ADVERSE EVENTS REPORTING SYSTEM (VAERS)

The Vaccine Adverse Event Reporting System (VAERS) is a national vaccine safety surveillance program co-sponsored by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). VAERS collects and analyzes information from reports of adverse events following immunization. A copy of the VAERS reporting form can be found online: https://vaers.hhs.gov/esub/index.

VAERS encourages the reporting of any significant adverse event that occurs after the administration of any vaccine licensed in the United States. You should report clinically significant adverse events, even if you are unsure whether a vaccine caused the event. The National Childhood Vaccine Injury Act (NCVIA) requires health care providers to report:

- Any event listed by the vaccine manufacturer as a contraindication to subsequent doses of the vaccine; and
- Any event listed in the Reportable Events Table that occurs within the specific time period after vaccination. A copy of the Reportable Events Table can be found online: https://vaers.hhs.gov/resources/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

Both the CDC and the FDA review data reported to VAERS. The FDA reviews reports to assess whether a reported event is adequately reflected in product labeling, and closely monitors reporting trends for individual vaccine lots. The CDC encourages all physicians to report any reaction following vaccination to VAERS, regardless of whether or not the physician believes that the vaccine caused the reaction. Reports sent to the VAERS Program that also make reference to non-vaccine pharmaceutical products are shared with MedWatch, the FDA's drug safety surveillance system.

To obtain additional information about VAERS:

- Send e-mail inquiries to info@vaers.org;
- Visit the VAERS website: https://vaers.hhs.gov/index;
- Call the toll-free VAERS information line at (800) 822-7967; or
- Fax inquiries to the toll-free information fax line at (877) 721-0366.

SAFE INJECTION PRACTICES

The investigation of four large outbreaks of hepatitis B and hepatitis C virus among patients in ambulatory care facilities in the United States identified a need to define and reinforce safe injection practices. The four outbreaks occurred in a private medical practice, a pain clinic, an endoscopy clinic, and a hematology/oncology clinic. The primary breaches in infection control practice that contributed to these outbreaks were 1) reinsertion of used needles into a multiple-dose vial or solution container (e.g., saline bag) and 2) use of a single needle/syringe to administer intravenous medication to multiple patients.

In one of these outbreaks, preparation of medications in the same workspace where used needle/syringes were dismantled also may have been a contributing factor. These and other outbreaks of viral hepatitis could have been prevented by adherence to basic principles of aseptic technique for the preparation and administration of parenteral medications. These include the use of a sterile, single-use, disposable needle and syringe for each injection given and prevention of contamination of injection equipment and medication. The CDC launched a national education campaign: http://www.oneandonlycampaign.org/.

Improper use of syringes, needles, and medication vials during routine healthcare procedures, such as administering injections have resulted in one or more of the following:

- Transmission of blood borne viruses, including hepatitis B and hepatitis C to patients;
- Notification of thousands of patients of possible exposure to blood borne pathogens and recommendation that they be tested for hepatitis B, hepatitis C, and HIV;
- Referral of providers to licensing boards for disciplinary action;
- Malpractice suits filed by patients.

These unfortunate events serve as a reminder of the serious consequences of failure to maintain strict adherence to safe injection practices during patient care. Injection safety and other basic infection control practices are central to patient safety. All healthcare providers are urged to carefully review their infection control practices and the practices of all staff under their supervision. In particular, providers should ensure that staff:

- Never administer medications from the same syringe to more than one patient, even if the needle is changed;
- Do not enter a vial with a used syringe or needle.

Hepatitis B, hepatitis C, and HIV can be spread from patient to patient when these simple precautions are not followed. Additional protection is offered when medication vials can be dedicated to a single patient. It is important that:

- Medications packaged as single-use vials never be used for more than one patient;
- Medications packaged as multi-use vials be assigned to a single patient whenever possible;
- Bags or bottles of intravenous solution not be used as a common source of supply for more than one patient;
- Absolute adherence to proper infection control practices is maintained during the preparation and administration of injected medications.

VACCINE ADMINISTRATION

How to Administer Vaccines:

There are several resources available on how to administer vaccinations to persons of all ages. These include:

- Immunization Action Coalition – http://www.immunize.org/handouts/administering-vaccines.asp
- Epidemiology and Prevention of Vaccine-Preventable Disease (Pink Book)
  - Appendix D
  - http://www.cdc.gov/vaccines/pubs/pinkbook/index.html
- EZ IZ: http://eziz.org/eziz-training/

Immunization Schedule:

The NSIP requires all enrolled providers to follow the Advisory Committee on Immunization Practices (ACIP) schedule. Alternative immunization schedules are not allowed unless for a specific medical circumstance.

ACIP schedules can be viewed, downloaded and printed online: http://www.cdc.gov/vaccines/schedules/index.html

COMPLIANCE SITE VISITS

All enrolled providers/clinics/facilities must be reviewed periodically as a condition of continued enrollment in the Nevada Cocooning Program:

Compliance site visits are performed to evaluate provider compliance with the Nevada Cocooning Program Protocols and address any deficiencies. Nevada State Immunization Program staff or its representatives will contact the providers/clinics for scheduling of the site visit and review. If requested by the reviewer, the provider may need to respond to areas of non-compliance with a written corrective action plan. This corrective action plan is normally due within two (2) weeks of the request; delays in submitting a corrective action plan may result in temporary suspension of vaccine shipments.

NSIP staff, or an authorized representative, may conduct one or more of the following types of visits during a calendar year:

- **Enrollment or Re-enrollment Visit** – an enrollment visit includes education about the NSIP guidelines, including proper vaccine storage and handling techniques. This visit is also an opportunity to establish a working relationship with the NSIP representative. A re-enrollment visit will be made to providers/clinics that have:
    - Requested to be reactivated in the program;
    - Moved into a new facility; and/or
    - Been delinquent in re-enrolling during the annual process.
- **Compliance Site Visit** – a formal review of compliance with NSIP standards that is conducted at least once every two (2) years. The CDC "Compliance Site Visit Questionnaire" is completed. A review is conducted of a sampling of patient charts for documentation of vaccine administration.
- **Compliance Follow-Up Visit** – an assurance check of issues of concern that arose from the Compliance Site Visit. This follow-up visit normally occurs within four to six (4-6) weeks of the original visit. The medical director who signed the enrollment forms, or their designee is strongly recommended to attend the follow-up session.
- **Education Visit** – a visit that occurs when provider sites undergo significant staff turnover or to assist in an area for improvement, such as a review of the ACIP schedule, or developing written vaccine storage and handling plans.

CONSEQUENCES OF NON-COMPLIANCE

If an enrolled provider is found to be non-compliant with these Protocols, then vaccine shipments to the provider may be suspended until a corrective action plan is submitted or other necessary steps are taken to correct deficiencies. Failure to adequately correct serious deficiencies, such as those that jeopardize vaccine effectiveness, can result in termination of the provider from active participation in the Nevada Cocooning Program.

The following actions may be taken and special provider status assigned:

Temporarily Inactive

1. Vaccine integrity cannot be assured because the temperature in the refrigerator was recorded as 32°F or 0°C, or lower, at any given time without documented immediate corrective action; no thermometer in vaccine storage unit; no documentation of daily temperature checks for vaccine storage unit. **When vaccine storage problems cause vaccine to be compromised, shipments may be suspended until the practice provides a one-week temperature log from the storage unit, proving that it is capable of sustaining appropriate storage temperatures.** Once reactivated, practices may need to provide weekly temperature logs to evaluators for up to two (2) months to ensure that vaccine storage problems have been resolved.
2. Refusal to cooperate with NSIP staff requests for compliance site visits, records, information or corrective action plans needed to satisfy program requirements.

Not Active (INACTIVE)

1. The provider requests in writing to withdraw from program participation;
2. The provider is unwilling or has refused to comply with program requirements; or
3. The provider refuses to meet reasonable "standard of care" expectations by not adhering to the current ACIP Recommended Immunization Schedules.

FRAUD AND ABUSE POLICY

The NSIP Fraud & Abuse Policy provides guidance in the monitoring and prevention of fraud and/or abuse of state supplied vaccines. This policy is consistent with standards established in the policy on fraud and abuse by the U.S. Centers for Disease Control and Prevention (CDC) located at http://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/fraud.html.

This policy applies to any fraud, abuse, and/or waste of federal and/or state supplied vaccines involving Nevada State Immunization Program enrolled providers.

Purpose of the Fraud and Abuse Policy

The purpose of this policy is to provide a standard operating procedure for prevention, detection, investigation and resolution of all suspected cases of provider fraud and/or abuse. All hospitals and obstetric providers are required to be enrolled in the Nevada Cocooning Program by completing and returning a signed *Nevada Cocooning Program Agreement to Participate* which specifies program requirements.

Suspected fraud and/or abuse will be identified by several mechanisms, which may include, but not be limited to:

- Vaccine Request and Accountability Reports;
- NSIP in compliance site or NSIP education visits;
- Responses to high priority questions on the CDC Site Visit Questionnaire;
- Verbal or written reports from provider staff;
- Verbal or written complaints from patients;
- Inconsistencies in reporting of vaccines in the immunization registry (Nevada WebIZ).

Reports of suspected fraud and/or abuse will be investigated immediately

For the purposes of this Fraud and Abuse Policy, the following definitions will be used:

Fraud: defined in the Code of Federal Regulations, Title 42, Part 455, Section 455.2 (42 CFR 455.2) as an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law.

Abuse: defined in 42 CFC 455.2 as provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid Program, (and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient); or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid Program.

Fraud and Abuse Policy Components

All suspected cases of fraud and/or abuse will be reviewed by the following Immunization Program staff: Program Manager, Provider Quality Assurance Manager, Vaccine Manager, and other staff assigned to assist. Available data and complaints will be reviewed. If staff believes that fraud and/or abuse is suspected then further examination will take place.

The NSIP will track all suspected cases of fraud and/or abuse in a database to monitor and document all actions taken on allegations related to fraud and/or abuse, including actions taken to address identified situations.

The NSIP Office Manager (Administrative Assistant 3) in collaboration with the Program Manager will serve as the primary person to: a) make the referral and b) notify appropriate governmental agencies. The Vaccine Manager and Provider Quality Assurance Manager will serve as the first and second back-up referral positions.

Examples of Fraud and Abuse

1. Examples of actions that might constitute potential fraud and/or abuse:
    a. Selling or otherwise misdirecting publicly supplied vaccine;
    b. Billing a patient or third party for publicly supplied vaccine;
    c. Charging more that the established maximum regional charge for administration of a publicly supplied vaccine;
    d. Denying an eligible patient publicly supplied vaccine because of their inability to pay the administration fee;
    e. Failing to implement any of the NSIP's provider enrollment requirements;
    f. Failing to maintain records related to the Nevada Cocooning Program;
    g. Failing to fully account for publicly supplied vaccines;
    h. Failing to properly store and handle publicly supplied vaccines;
    i. Ordering publicly supplied vaccine in quantities or patterns that do not match the provider's profile or otherwise involve over-ordering; and
    j. Wasting of publicly supplied vaccine due to negligence or non-compliance.

2. All reported cases of intentional fraud and/or abuse by NSIP-enrolled providers will be investigated appropriately.

Wasted Vaccine Definitions

Wasted vaccine is listed above under *Examples of Fraud and Abuse*. Any vaccine that cannot be used is considered "wasted," including expired vaccine, spoiled vaccine, or vaccine which is unaccounted for. Wasted vaccine that is determined by the NSIP to have been wasted due to negligence or non-compliance on the part of the provider may be subject to dose-for-dose restitution.

1. **Expired** – vaccine that is past its expiration date.

2. **Spoiled** – any vaccine that exceeds the limits of approved cold chain procedures or is pre-drawn and not used within acceptable time frames (an opened multi-dose vial is not spoiled until the expiration date has passed), or vaccine that has been delivered in non-viable condition.

3. **Unaccounted For** – any vaccine that has been lost in transit by the distributor or manufacturer, or vaccine not accounted for by monthly usage and inventory reports. This can be reflected by usage data or inventory discrepancies that reflect unaccounted for vaccine.

Wasted Vaccine Scenarios

This list includes but is not limited to the following scenarios:

1. **Non-Preventable Vaccine Loss**

   No action will be taken to enforce dose-for-dose restitution if the NSIP determines the vaccine loss was not due to negligence or non-compliance on the part of the provider.

   a. The carrier (UPS, FedEx, etc.) does not deliver the vaccines in a timely manner. Before making the determination that the vaccine is non-viable, the provider must first contact the vaccine manufacturers.
   b. An alert/alarm company does not notify the provider of a vaccine storage unit malfunction.
   c. Power is interrupted or discontinued due to a [storm, earthquake, etc.] natural or man-made disaster.
   d. Vaccine is moved to a nearby facility due to anticipated inclement weather, the facility experiences a power failure and the vaccine is later deemed to be non-viable.
   e. A vial is accidentally dropped/broken.
   f. Vaccine that is drawn at the time of the visit, but is not administered due to parental refusal or a change in physician orders.
   g. Extraordinary situations not listed above which the NSIP deems to be beyond the provider's control.

2. **Preventable Vaccine Loss**

   Loss Due to Negligence: Below is a list of situations that may be considered "provider negligence" and may require dose-for-dose restitution. Situations that occur which are not listed here will be considered on a case-by-case basis by the NSIP Program Manager. Action may be taken by the NSIP to enforce dose-for-dose restitution if it is determined that vaccine loss was due to negligence on the part of the provider.

   a. Failure to establish and follow an "Office Vaccine Management Plan."
   b. Failure to rotate or transfer vaccine that results in expired vaccine, and the NSIP was not notified at least three (3) months before the vaccine's expiration date.
   c. Pre-drawing vaccine before screening patients.
   d. Leaving vaccine out of the vaccine storage unit so it becomes non-viable.

e. Vaccine stored improperly (e.g., refrigerating vaccine that should be frozen or freezing vaccine that should be refrigerated, etc.).
f. Leaving a vaccine storage unit unplugged or an electrical breaker switched off. A "DO NOT UNPLUG" sticker is required at each outlet and circuit breaker that is powering a vaccine storage unit.
g. Leaving a vaccine storage unit door open or ajar, whether by staff, contractors or guests.
h. Improper maintenance of recommended temperatures resulting in vaccine spoilage, including prolonged storage of vaccines when out of range temperatures are recorded. *NOTE: Temperatures recorded on NSIP Temperature Logs will be considered official when making vaccine viability decisions. Also, a thermometers margin of error will not be considered when temperatures are recorded at or below 35°F / 2°C or above 46°F / 8°C.*
i. Failing to act according to the Office Vaccine Management Plan during a power outage or other emergency situation.
j. Transporting publicly supplied vaccine in a manner that does not maintain the cold chain appropriately at all times.
k. Shipping publicly supplied vaccine at any time (shipping is different from "transporting").
l. Failure to notify the NSIP when office hours change or the practice moves, resulting in vaccines being undeliverable and consequently spoiled.
m. Failure to maintain alarm/alert devices properly.
n. Relying solely on electronic temperature monitoring and not manually checking and documenting temperatures twice daily.
o. Failure to be available to receive and properly store vaccine shipments per established office hours.
p. Failure to use approved vaccine storage units. **Dorm style units are NOT acceptable**.

Loss Due to Non-Compliance: Publicly supplied vaccine not accounted for by monthly usage and inventory reports. This can be reflected by usage data or inventory discrepancies that reflect lost vaccine supply. Action may be taken by the NSIP to enforce dose-for-dose restitution if it is determined that vaccine loss was due to non-compliance on the part of the provider. Examples include:

a. Failure to document vaccine usage or inaccuracy in reporting vaccine usage or inventory received on the:
    i. Vaccine Request and Accountability Report, or
    ii. Vaccine Lot Number Inventory Report.

b. Accepting reimbursement from insurance companies or patients for publicly supplied vaccine as evidenced by:
    i. Administering publicly supplied vaccine and subsequently billing the patient's insurance for the cost of the vaccine;
    ii. Charging the patient for the cost of the vaccine; and/or
    iii. Charging a Medicaid recipient any fee at all.

Providers are encouraged to have insurance policies in place to cover the cost of wasted/spoiled vaccine

Course of Action for Vaccine Restitution

The Nevada State Immunization Program allows for up to a 5% vaccine wastage loss on an annual basis. This means that if a provider received 100 doses annually, up to 5 doses may be allowable in wastage, with no consequences. Anything above this threshold may be due to negligence or non-compliance and therefore the provider may be subject to replace the vaccine on a dose-for-dose basis using the most current vaccine costs: http://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/index.html.

Who Will Investigate?

The NSIP will examine all suspected fraud and/or abuse cases involving Nevada Cocooning Providers. When the NSIP identifies suspicious activity via IIS data or written or verbal reports, then the program will review the case. If the NSIP determines that further investigation is warranted or justified, then the case will be analyzed by program staff and a determination will be made.

Criteria that will be considered during a fraud and abuse investigation

- Past program compliance by the provider up to the time of the reported incident;
- Compliance to vaccine storage and handling requirements;
- How the incident was reported/identified;
- Length of time the situation was/has been occurring;
- Inadvertent or purposeful financial gain by the provider;
- The amount of publicly supplied vaccine that is wasted/spoiled;
- The provider's willingness to replace dose for dose the lost publicly supplied vaccine with privately purchased vaccine; and
- The provider's willingness to participate in the education visit referral and post-education follow-up.

If an instance of fraud and/or abuse is determined to result from an excusable lack of knowledge or understanding of the NSIP Protocols, then secondary education and a corrective action plan will be implemented. If an instance of fraud and/or abuse is determined to be intentional and the provider has received financial benefits from the behavior, then the situation will require immediate review. The provider will be temporarily suspended pending the outcome of a more in-depth review. If an enrolled provider is not compliant with NSIP Protocols or fraud and/or abuse is suspected or reported, then vaccine shipments to the provider may be suspended until a corrective action plan is submitted. Corrective actions may include more frequent site visits and monitoring of records or replacement of vaccine damaged through provider negligence at provider expense. Failure to adequately correct serious deficiencies may result in enrolling the provider into a formal education process, termination of provider participation in the Cocooning Program, or in the case of suspected fraud, referral for criminal prosecution or civil resolution.

Detection and Monitoring of Fraud and Abuse

All provider sites will include the examination and analysis of Section I of CDC's Compliance Visit Questionnaire. All compliance site visit reports submitted by field staff, including all documented cases of potential of fraud and/or abuse, all site findings and site recommendations, will be reviewed by the Provider Quality Assurance Manager and, if appropriate, by the Vaccine Manager and then referred to the Program Manager as appropriate.

Failure to Comply with Nevada Cocooning Program Requirements

All hospital and obstetric providers must enroll into the Nevada Cocooning Program annually. This includes completing and submitting the signed *Nevada Cocooning Program Agreement to Participate*. This enrollment packet includes all the mandatory components of program participation and can be found online: http://dpbh.nv.gov/Programs/Cocooning/Cocooning_-_Home/.

Consequences

Any provider found guilty of fraud and/or abuse will be subject to:

- Replacement of publicly supplied vaccine on a dose-for-dose basis;
- Termination from the Nevada Cocooning Program; and
- Other consequences deemed appropriate by the Nevada Division of Public and Behavioral Health.

Appeals Process

For decisions and findings rendered by the Nevada State Immunization Program a provider must follow guidance for the appeals process.

Per Nevada Revised Statutes (NRS) 439.200, 233B.130, and corresponding regulation in Nevada Administrative Code (NAC) 439.300 – 439.395, providers have the right to appeal decisions made by the Nevada State Immunization Program in regards to termination from the VFC Program or financial responsibility to replace vaccines.

If the Nevada State Immunization Program has made the decision to invoice a provider for loss of vaccine or terminate a provider from the VFC Program, then the provider will receive a notice of disciplinary action from the program. If the provider wishes to appeal the notice, then the provider has 10 days to submit an appeal to dispute the notice. If an appeal is not received within 10 days of notice, then the decision is considered final.

If an appeal is received within 10 days of the notice, then the Nevada State Division of Public and Behavioral Health Administrator will assign a hearing officer for a formal proceeding. A formal hearing will be set and a decision will be made by the hearing officer based on evidence provided by both the Nevada State Immunization Program and the provider. All decisions made by the hearing officer are final unless either party wishes to seek judicial review in a court of law.